IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL PLAINTIFFS LISTED IN EXHIBIT A TO PLAINTIFFS' AMENDED MOTION**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' AMENDED MOTION TO LIMIT THE OPINIONS AND TESTIMONY OF SALIL KHANDWALA, M.D.

Salil Khandwala, M.D., is board certified in Obstetrics and Gynecology, with a specialty certification in Female Pelvic Medicine and Reconstructive Surgery. He has performed over 2,000 surgical implantations of mid-urethral slings, has been treating pelvic organ prolapse (POP)—including with synthetic mesh systems—since 1997, and has performed numerous mesh revision surgeries. He has designed and participated in clinical trials involving mesh sling implants and other pelvic reconstructions. He has published in the fields of urinary incontinence and genital organ prolapse, and has broad teaching experience in these fields.

Despite Dr. Khandwala's extensive qualifications, Plaintiffs seek to exclude his opinions about: (1) the Instructions for Use (IFUs) and Patient Brochures for the TVT, TVT-O, and TVT-S; (2) biocompatibility and mesh physical properties, including degradation, shrinkage, contraction, particle loss, and porosity; and (3) design of the TVT, TVT-O, and TVT-S.[1] Plaintiffs' motion should be denied because:

[1] Plaintiffs have incorporated by reference their *Daubert* challenge to Dr. Khandwala's opinions filed in Wave 1. Pls.' Mem. (Dkt. 2470) at 1 (incorporating Plaintiffs' Wave 1 Khandwala

- **Dr. Khandwala is qualified to testify about the IFUs and Patient Brochures, and fully supported his opinions with a reliable methodology**. Dr. Khandwala is qualified to offer opinions about whether there are additional risks of which pelvic-floor surgeons were not aware—and that are unique to Ethicon's TVT devices—that should have been included in the IFUs and Patient Brochures. His opinions are supported by a reliable methodology because they are based on his extensive experience, review of the medical literature and FDA regulations and statements, and discussions with colleagues.

- **Dr. Khandwala is qualified to offer opinions on biocompatibility and mesh physical characteristics, and his opinions are supported by a reliable basis**. This Court has found numerous similarly experienced surgeons qualified to testify on these topics. Also, review of dozens of high-quality scientific articles, FDA sources, and statements of leading surgical associations constitutes a reliable methodology to support his opinions.

- **Dr. Khandwala is qualified to testify regarding the design of the TVT, TVT-O, and TVT-Secur**. In addition to his clinical experience and comprehensive review of the medical literature, Dr. Khandwala has relevant design-related experience to support his opinions on these topics.

Plaintiffs' challenges to Dr. Khandwala's opinion testimony are meritless under Rule 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Defendants Ethicon, Inc. and Johnson & Johnson (Ethicon) therefore ask that Plaintiffs' motion be denied.

ARGUMENTS AND AUTHORITIES

I. Dr. Khandwala Is Qualified to Testify About the IFUs and Patient Brochures, and His Underlying Methodology for His Opinions Is Reliable.

Dr. Khandwala seeks to testify about the potential risks of the TVT, TVT-O, and TVT-Secur—both those risks that attend *any* pelvic reconstruction (of which surgeons are aware) and those that are specific or unique to Ethicon's TVT products based on valid scientific support. And he seeks to compare that knowledge with the warnings in the TVT products' IFUs and Patient Brochures, as well as with the additional warnings Plaintiffs argue Ethicon should have

---

motion and memorandum, Dkts. 2003 and 2004, respectively). In response, Defendants incorporate by reference their Opposition to Plaintiffs' Wave 1 motion (Dkt. 2175).

provided. Based on his analysis, Dr. Khandwala opines that none of the alleged risks identified by Plaintiffs' experts should have been added to the IFUs and related Patient Brochures; therefore, the warnings provided for the Ethicon TVT devices were adequate. Dr. Khandwala is qualified to provide this opinion and his methodology is reliable.

A. Dr. Khandwala Is Qualified to Testify About Surgeons' Awareness of Risks Associated with All Pelvic Surgeries and Risks Unique to TVT Devices.

Surgeons who perform pelvic reconstructions, including mesh sling implantations, are aware of the associated potential risks present in all such surgeries. That information will be helpful to juries assessing warning adequacy because a manufacturer has no duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §2, cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users." *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§ 388(b), 402A, cmt. j; *Roney v. Gencorp*, 654 F. Supp. 2d 501, 507 (S.D.W. Va. 2009) (adopting "sophisticated user" defense in §388). In fact, the FDA has said that information may be omitted from labeling "if, but only if, the article is a device for which directions, hazards, warnings and other information are *commonly known* to practitioners licensed by law to use the device." 21 C.F.R. § 801.109(c) (emphasis added).

Here, the device IFUs restrict their use to surgeons familiar with traditional surgical techniques used to treat stress urinary incontinence. *E.g.*, Ex. 1, TVT IFU, ETH.MESH.03427881 ("Users should be familiar with surgical technique for bladder neck suspensions and should be adequately trained in implanting the GYNECARE TVT System before employing the GYNECARE TVT Device"); Ex. 2, TVT-O IFU, ETH.MESH.02340907

("Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in the GYNECARE TVT Obturator procedure before employing the GYNECARE TVT Obturator Device"); Ex. 3, TVT-Secur IFU, ETH.MESH02340587 ("Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in the GYNECARE TVT SECUR System before using"). Accordingly, juries must consider the adequacy of the TVT products' warnings in light of the skill and experience of this particular surgical community.

Dr. Khandwala is qualified to testify about risks of all pelvic reconstructions of which surgeons are already aware based on their training and experience. In *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 720–21 (S.D.W. Va. 2014), this Court held that plaintiffs' expert urologist, Dr. Blaivas, could offer opinions about what was known about mesh complications and warnings discussed by educators in lectures addressing the use of mesh for surgical treatment of stress incontinence. The Court concluded that, as a urologist, Dr. Blaivas was "certainly fit to testify what other physicians knew as it relates to the standard of care for designing a mesh product and warning about its potential risks." *Id.* at 721.

Dr. Khandwala's extensive experience qualifies him to testify on these topics. He has been teaching and practicing in the fields of urogynecology and reconstructive pelvic surgery for almost 20 years. Ex. B to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT/TVT-O Report at 2–3. He is board certified in Obstetrics and Gynecology, and was among the first surgeons certified in Female Pelvic Medicine and Reconstructive Surgery (FPMRS), a specialty approved in the spring of 2011. *Id.* at 4. As part of the NIH's Urinary Incontinence Treatment and Pelvic Floor Disorders Networks, he has designed and participated in landmark clinical trials evaluating sling procedures and other pelvic reconstructions. *Id.* at 3–4. He has performed over 2,000 surgical

implantations of mid-urethral slings—roughly 800 of which involved Ethicon's TVT, TVT-O, or TVT-Secur products. *Id*. at 3. He has been performing POP reconstructions, using methods ranging from native tissue repairs to implantation of synthetic mesh systems from Ethicon and other manufacturers, since 1997. *Id*. He has also performed roughly 25 mesh revision surgeries. Ex. D to Am. Pls.' Mot. (Dkt. 2469–1), Khandwala 7/8/16 Dep. Tr. 70:21–71:2.

Drawing on this experience, Dr. Khandwala has long trained other surgeons in the implantation of synthetic mesh slings and related procedures. In particular, he has trained over 100 OB/GYN residents, as well as two fellows in the new FPMRS specialty, and teaches related courses both domestically and internationally. Ex. B to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT/TVT-O Report at 4. He also has trained pelvic reconstruction surgeons in the proper procedures for implanting Ethicon synthetic mesh products through proctorships at his facility and others, and by conducting cadaver labs. Ex. 4, Khandwala 7/8/16 Dep. Tr. 28:15–29:14. He has led discussion groups at annual meetings and served on boards of Ethicon's main proctors available to answer questions regarding proper implantation techniques from surgeons in the field. *Id*. 102:16–104:3. He has used medical devices from several manufacturers and read many IFUs over the years. Ex. B to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT/TVT-O Report at 3, 34. Although he is not required to be familiar with FDA rules or federal regulations to give this testimony, *see, e.g.*, *Winebarger v. Boston Sci. Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *15 (S.D.W. Va. Apr. 24, 2015), he nonetheless familiarized himself with regulations governing the types of risk information that may be omitted from a product's labeling. Ex. B to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT/TVT-O Report at 33.

In addition to qualifying him to opine that certain risks need not be warned about because they are well known to pelvic-floor surgeons, Dr. Khandwala's extensive clinical experience

qualifies him to opine that there is no valid scientific evidence for other alleged risks identified by Plaintiffs' experts. *Id*. at 32-35. "[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger*, 2015 WL 1887222, at *15. Based on his experience described above, Dr. Khandwala is qualified to offer such an opinion from a clinical perspective. *See id.* That Dr. Khandwala is not a regulatory expert, has not worked for the FDA, and has not drafted an IFU or Patient Brochure, Am. Pls.' Mem. (Dkt. 2470) at 3–5, is beside the point. *See id.* (finding Dr. Shull qualified to give opinions on product labeling based on his clinical experience because his testimony did not touch on regulatory issues); *Huskey*, 29 F. Supp. 3d at 703–04, 719 (Drs. Rosenzweig and Blaivas were adequately experienced physicians to testify to risks of surgery and whether the risks were addressed in the IFU despite lack of expertise in FDA regulations or standards governing device warnings); *Trevino v. Boston Sci. Corp.*, No. 2:13-cv-01617, Slip Copy 2016 WL 2939521, at *13–14 (S.D.W. Va. May 19, 2016) (Dr. Shull permitted to testify on adequacy of DFUs "from a clinical perspective").

B. Dr. Khandwala's Opinions Are Supported by a Reliable Methodology.

Dr. Khandwala concluded that the additional warnings proposed by Plaintiffs' experts involve risks of which pelvic-floor surgeons were already aware or are alleged risks without valid scientific support.[2] Ex. B to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT/TVT-O Report

[2] The Court should reject Plaintiffs' assertion that "Dr. Khandwala essentially conceded that the IFU for the TVT-S was inadequate because physicians needed to supplement the instructions with additional documents to clarify the IFU." Am. Pls.' Mem. (Dkt. 2470) at 7. The TVT-S Monograph to which Plaintiffs refer was a training booklet for surgeons on proper placement technique. Ex. 4, Khandwala 7/8/16 Dep. Tr. 108:9-112:6. The IFU is not intended to—nor could

at 32-35. Dr. Khandwala therefore opined that the IFUs "adequately describe the risks that are specific and/or unique to TVT and TVT-O." *Id.* at 32.[3] Specifically, Dr. Khandwala disagreed that "Ethicon was required to warn surgeons that an operation in the vagina, including the TVT and TVT-O, could result in things like pelvic pain, dyspareunia, scarring, and vaginal shape changes, all of which can be permanent," because "[a]ll surgeons performing vaginal surgery, including the TVT or TVT-O, are expected to be well aware of these known potential surgical complications." *Id.* at 34. Dr. Khandwala also disagreed that "Ethicon was required to warn surgeons that revision might be necessary, that a permanent implant may be difficult to remove and that revision might not alleviate symptoms" as surgeons in this field are aware of these risks as well. *Id.* And Dr. Khandwala further opined that dyspareunia need not be included in the IFUs and related Patient Brochures because "[t]he incidence of dyspareunia due to the TVT and TVT-O sling is less than 1% . . . ." *Id.* at 34 (citing Tommaselli 2015).

In support of his opinions, Dr. Khandwala relied on his experience performing hundreds of TVT procedures and treatment of patients who had slings implanted by other doctors, his outcome analysis of the procedures in clinical trials, his participation in and teaching of cadaver courses, his live-surgery experience teaching visiting doctors or residents on performing the TVT and TVT-O procedures, and his interaction with fellow surgeons at these events. Ex. B to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT/TVT-O Report at 32–33. He relied on other resources as well, including:

---

it—replace the surgeon's medical training. Nor can it cover all possible implantation techniques, which necessarily vary based on not only the individual surgeon's skill and experience, but also the individual patient's habitus, health status, and other factors. *See id.* at 131:23–133:11.

[3] Dr. Khandwala's opinions regarding the TVT-Secur are similar. Ex. C to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT-Secur Report at 61–66.

- his review of the published medical literature on the success and complication rates associated with the TVT and TVT-O, which includes "over 1,000 TVT studies, over 150 randomized controlled trials on TVT and TVT-O, and multiple meta-analyses" (*id*. at 33);

- information he learned at medical conferences and professional society meetings he has regularly attended throughout his career (*id*.);

- his review of 21 C.F.R. § 801.109(c) and the FDA's "Blue Book Memo," both of which permit the omission of risk information commonly known to practitioners licensed to use the device (*id*. at 33); and

- the FDA's 2013 statement, "Considerations about Surgical Mesh for SUI," which concluded that "safety and effectiveness of multi-incision slings is well-established," and that, "[w]ith the exception of mesh erosion," the most common complications reported in patients with mesh sling implants, including pain and dyspareunia, are complications of non-mesh surgical repairs for SUI as well. *Id*. at 33 & n.1.

Therefore, contrary to Plaintiffs' assertion, Dr. Khandwala does not rely solely "on his own practice and experience." Am. Pls.' Mem. (Dkt. 2470) at 5.[4]

Plaintiffs' attempt to shoehorn Dr. Khandwala's opinions into the Court's rulings in *Tyree* and *Waltman*, Am. Pls.' Mem. (Dkt. 2470) at 3–5, fails. Those cases are distinguishable. In both, the Court excluded testimony from defense experts who offered opinions that the warnings were adequate merely because they included risks that the experts observed in their own practices. *See Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 584 (S.D.W. Va. 2014) ("The plaintiffs' experts address a discrete risk which they have personally observed, while BSC's experts' opinions attempt to encompass all possible risks, none of which they have personally observed."); *Waltman v. Boston Sci. Corp*., No. 2:12-CV-691, 2016 WL 3198322, at *17

[4] Plaintiffs' statement that "Dr. Khandwala opines that the IFUs are adequate because he personally hasn't seen the adverse events that were not included in the relevant and earlier versions of the IFUs," Am. Pls.' Mem. (Dkt. 2470) at 7, is both a misrepresentation of the bases for Dr. Khandwala's opinions, *see supra*, and lacking support. The deposition testimony cited by Plaintiffs relates to fraying, not to any adverse events experienced by patients. Ex. D to Am. Pls.' Mot. (Dkt. 2469–1), Khandwala 7/8/16 Dep. Tr. 146:1–147:1.

(S.D.W. Va. June 8, 2016) ("without additional expertise in the specific area of product warnings, a doctor . . . is not qualified to opine that a product warning was adequate merely because it included risks he observed in his own practice"). While a single physician's experience may not be sufficient, Dr. Khandwala has employed a sound methodology here by relying upon a large pool of scientific literature and studies—combined with clinical experience as well as review of FDA regulations and statements, and discussions with colleagues—to support his conclusions that certain risks need not be included in the warning because they do not occur, or are not unique to pelvic mesh devices and are well known to surgeons. Ex. B to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT/TVT-O Report at 32–34. Indeed, when Plaintiffs' experts have concluded that risks do occur based on such support, they are allowed to testify that the risk should have been included in the mesh warnings. It stands to reason that an expert employing this same methodology, while reaching a different conclusion, has also provided admissible testimony. That Plaintiffs may disagree with Dr. Khandwala's conclusion can be addressed on cross-examination. *Tyree*, 54 F. Supp. 3d at 532.

In summary, Dr. Khandwala is qualified and used a reliable methodology to support his opinions about the warnings in the TVT products' IFUs and related Patient Brochures. His testimony should be admitted under *Daubert* and Rule 702.

II. Dr. Khandwala's Opinions on Biocompatibility and Mesh Physical Characteristics Are Admissible.

A. Dr. Khandwala Has the Necessary Qualifications.

Dr. Khandwala proposes to testify that TVT mesh does not fray, curl, rope, or experience particle loss (Ex. B to Am. Pls.' Mot. (Dkt. 2469-1) Khandwala TVT/TVT-O Report at 36); it does not degrade (*id*. at 36–37); it does not shrink (*id*. at 38); and it maintains its macroporous construction after implantation (*id*.). Dr. Khandwala is well qualified to testify on the properties

and characteristics of the mesh used in the TVT, TVT-O, and TVT-Secur. As explained, he is an accomplished urogynecologist, board certified not only in Obstetrics and Gynecology but also in the nascent specialty of FPMRS. He has extensive experience implanting these and other synthetic mesh slings, performing revision surgeries, investigating mesh slings and related products and procedures in clinical trials, publishing his findings, and training other surgeons in these procedures.

Despite these substantial qualifications, Plaintiffs wrongly argue that Dr. Khandwala is not qualified to testify about these issues because he is not a biomaterials expert, a pathologist, or a toxicologist; has not conducted bench testing on explanted mesh or polypropylene; has not published on degradation; and has not conducted studies or published on mesh porosity, flexibility, and stiffness. Am. Pls.' Mem. (Dkt. 2470) at 9–15. Contrary to Plaintiffs' argument, this Court has repeatedly allowed medical doctors with relevant clinical experience to offer opinions regarding the characteristics of polypropylene.

For instance, in *Trevino v. Boston Sci. Corp.*, No. 2:13-CV-01617, Slip Copy 2016 WL 2939521, at *44 (S.D.W. Va. May 19, 2016), the plaintiff argued that Dr. Michael Douso, a urogynecologist, was not qualified to testify about the physical properties of mesh and to offer opinions about degradation and similar topics because he was not a biomaterials or polymer science expert. In rejecting this challenge, the Court stated as follows:

> As to qualification, . . . Dr. Douso is a practicing urogynecologist, and he is board-certified in obstetrics and gynecology. He has extensive experience with BSC's products for treating SUI and POP, including use of the Prefyx and Uphold mesh sling devices. Dr. Douso has had extensive experience teaching minimally invasive surgical techniques and procedures to physicians across the United States, including implantation of the defendant's polypropylene mesh devices. Simply because Dr. Douso is not an engineer, chemist, or biomechanical expert does not render him unqualified to testify that he has not experienced mesh degradation, contraction, or a foreign body response in his practice. "One

> knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc.*, 878 F.2d at 799. I **FIND** that Dr. Douso's extensive experience qualifies him to testify that he has not experienced certain alleged physical properties in the defendant's Uphold and Prefyx devices.

2016 WL 2939521, at *44 (other citations omitted); *see also id.* at *5 (finding that urologist Niall Galloway's "clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage, and contraction"); *Huskey*, 29 F. Supp. 3d at 706-07, 735 (rejecting similar challenges to plaintiff expert Bruce Rosenzweig, M.D., and defense expert urogynecologist Harry Johnson, M.D.); *Tyree*, 54 F. Supp. 3d at 585 (rejecting similar challenge of defense expert Lonny Green, M.D.); *Jones v. C. R. Bard, Inc.*, No. 2:11–cv–00114, at 6-9 [Dkt. 391] (S.D.W. Va. Jan. 6, 2014).

Dr. Khandwala has similar experience to these experts. The Court should therefore deem him qualified to offer his opinions on the material properties of polypropylene.

B. Dr. Khandwala's Opinions About Mesh Characteristics Are Reliable.

In reaching his conclusions on mesh biocompatibility and mesh physical characteristics, Dr. Khandwala relied not only on his own education and clinical experience, but also on dozens of peer-reviewed scientific articles, FDA sources, and statements of the American Urogynecologic Society, American Urological Association, and National Institute of Health and Care Excellence in forming his opinions. *See* Ex. B to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT/TVT-O Report at 17–29, 33; *see also supra*. The scientific literature on which Dr. Khandwala relies includes randomized clinical trials as well as systematic reviews and meta-analyses. *See, e.g.*, Ex. B to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT/TVT-O Report at 17–25; *see also* Ex. C to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT-Secur Report at 32–38, 46–55. "A fundamental principle of evidence-based medicine . . . is that the strength of medical

evidence supporting a therapy or strategy is hierarchical. When ordered from strongest to weakest, systematic review of randomized trials (meta-analysis) is at the top, followed by single randomized trials, systematic reviews of observational studies, single observational studies, physiological studies, and unsystematic clinical observations." FED. JUDICIAL CTR., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 687, 723-24 (3d ed. 2011). Dr. Khandwala's opinions are based on the highest-level scientific evidence on the subject, as well as his nearly 20 years of clinical experience with these products. His opinions are reliable, relevant, and admissible. *See, e.g.*, *Huskey*, 29 F. Supp. 3d at 735 (finding degradation-related opinions of OB/GYN reliable where they were based on expert's clinical experience and review of relevant literature demonstrating a lack of evidence of clinically significant degradation).

Plaintiffs are wrong that Dr. Khandwala's opinions regarding degradation, contraction, shrinkage, and particle loss are too "general" to be admissible. Am. Pls.' Mem. (Dkt. 2470) at 12 (citing *Tyree*, 54 F. Supp. 3d at 580–81). Plaintiffs incorrectly assert that Dr. Khandwala's opinions are inadmissible because they are based on his clinical experience, during which he has not observed mesh degradation, fraying, or migrating particles. *Id*. at 12–13 (citing statements in Dr. Khandwala's reports and deposition testimony). Contrary to Plaintiffs' intimation, these are not the *only* bases for Dr. Khandwala's opinions. Instead, they are based on the type of clinical experience and extensive literature review that this Court has deemed sufficiently reliable to support mesh-characteristic opinions such as those offered by Dr. Khandwala. *See Huskey*, 29 F. Supp. 3d. at 735.

Plaintiffs further wrongly claim that Dr. Khandwala's opinions regarding porosity are "based on insufficient data." Am. Pls.' Mem. (Dkt. 2470) at 15 (citing Ex. D to Pls.' Mot. (Dkt. 2469–1), Khandwala 7/8/16 Dep. Tr. 145:18–24). The quoted testimony, however, merely

establishes that Dr. Khandwala has not conducted studies of or published on porosity or weight of synthetic mesh himself. Ex. D to Am. Pls.' Mot. (Dkt. 2469–1), Khandwala 7/8/16 Dep. Tr. 145:18–24. Plaintiffs do not address the substantial bases for Dr. Khandwala's opinions cited above, or the Court's rulings deeming comparable opinions of similarly qualified surgeons reliable. *See supra*.

Accordingly, Dr. Khandwala is qualified to provide opinions on biocompatibility and mesh physical characteristics, and supported his opinions with a reliable methodology. His testimony therefore is admissible.

III. Dr. Khandwala Is Qualified to Testify on Design-Related Topics.

Dr. Khandwala seeks to testify that the mesh material and design of the TVT products are appropriate and that designs proposed by Plaintiffs' experts that would use other mesh are not safer alternative designs. *E.g.*, Ex. B to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT/TVT-O Report at 29–31; Ex. C to Am. Pls.' Mot. (Dkt. 2469-1), Khandwala TVT-Secur Report at 70–72. Dr. Khandwala is qualified to offer these opinions based on his clinical experience and review of the medical literature. *See supra*; *see also Huskey*, 29 F. Supp. 3d at 721 (finding plaintiffs' expert urologist was "certainly fit to testify what other physicians knew as it relates to the standard of care for designing a mesh product"). Dr. Khandwala also has direct experience with the design of related products, having submitted drawings of design modifications to a mesh system to the system's manufacturer, and having received a provisional patent on another product. Ex. 4, Khandwala 7/8/16 Dep. Tr. 68:17–70:8. And, as Plaintiffs acknowledge, Dr.

Khandwala has reviewed Ethicon documents and "exhaustive studies" in the medical literature of numerous aspects of the Ethicon sling designs. Am. Pls.' Mem. (Dkt. 2470) at 17–18.[5]

Plaintiffs assert that Dr. Khandwala is not qualified to offer opinions regarding the design of the TVT, TVT-O, or TVT-Secur because he does not have experience "designing any of the relevant devices" and because his design experience relates to implant technique rather than mesh slings themselves. Am. Pls.' Mem. (Dkt. 2470) at 15–16; *see also id.* at 17 (citing *Tyree* and *Robbins*).[6] Plaintiffs' reliance on *Tyree* and *Robbins* is misplaced. The quoted passage in *Tyree* relates to the exclusion of design opinions of urogynecologist Dr. Culligan, who could only testify to having "design preferences," rather than design experience. *Tyree*, 54 F. Supp. 3d at 581. The Court found Dr. Culligan unqualified on this topic for similar reasons in *Robbins*. *See Robbins v. Boston Sci. Corp.*, No. 2:12-CV-01413, 2016 WL 3189248, at *22 (S.D.W. Va. June 7, 2016).

Dr. Khandwala's experience is more akin to that of Dr. Ostergard, a urogynecologist who was deemed qualified to offer design-related opinion testimony because he had performed "design theory work" for a mesh device manufacturer. *Tyree*, 54 F. Supp. 3d at 581.

[5] Plaintiffs attempt to discount this review by calculating he could only have spent "two minutes reviewing each of the documents on his reliance list." *Id.* at 18. Plaintiffs' calculation, based on the 72 hours he spent preparing his Wave 2 general report, is misleading. *See id.*; *see also* Ex. 4, Khandwala 7/8/16 Dep. Tr. 10:11–20, 13:12–16. Dr. Khandwala testified that the 72 hours did not represent the total time he had spent reviewing these materials, as he was very familiar with many of the documents in his reliance list, having reviewed them many times in the course of preparing for publication papers that he authored. *Id.* 45:5–21.

[6] Plaintiffs state that "any opinions Dr. Khandwala may have regarding the design of the mesh [are] unreliable," but do not support this statement with any citations or analysis. Am. Pls.' Mem. (Dkt. 2470) at 18.

Accordingly, the Court should deem Dr. Khandwala qualified to offer this testimony under *Daubert* and Rule 702.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that Plaintiffs' motion be denied in its entirety.

Respectfully submitted,

ETHICON, INC. AND
JOHNSON & JOHNSON

/s/ *Rita A. Maimbourg*
Rita A. Maimbourg
TUCKER ELLIS LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113-7213
Telephone: 216.592.5000
Facsimile: 216.592.5002
rita.maimbourg@tuckerellis.com

/s/ David B. Thomas
David B. Thomas (W.Va. Bar #3731)
THOMAS COMBS & SPANN PLLC
300 Summers St.
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
Telephone: 304.414.1807
dthomas@tcspllc.com

/s/ Christy D. Jones
Christy D. Jones
BUTLER SNOW LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
Telephone: 601.985.4523
christy.jones@butlersnow.com

CERTIFICATE OF SERVICE

I certify that on August 8, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ *Rita A. Maimbourg*
Rita A. Maimbourg
TUCKER ELLIS LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113-7213
Telephone: 216.592.5000
Facsimile: 216.592.5002
rita.maimbourg@tuckerellis.com